

CLAIMS

1. A test device for conducting an assay for the determination of an analyte in a sample, said device comprising (i) a housing (1, 2), and within said housing, (ii) a flow matrix (6) allowing liquid to be transported by capillary action and having at least one zone with immobilized capturing agent capable of directly or indirectly binding to the analyte, (iii) a liquid container (13) for sample liquid, and (iv) at least one liquid container (12) for liquid other than sample liquid, **characterized** in that the device further comprises (v) separation means (5) between the flow matrix (6) and the liquid containers (12, 13), wherein said separation means (5) are mounted in a movable relationship with the liquid containers to in a first position prevent liquid contact of the flow matrix (6) with the liquid containers (12, 13), and in a second position permit liquid receiving contact of the flow matrix (6) with the liquid containers (12, 13).
2. The test device according to claim 1, **characterized** in that the flow matrix (6) is flat and the liquid flow is lateral within said matrix.
3. The test device according to claim 1 or 2, **characterized** in that the flow matrix (6) is a membrane strip.
4. The test device according to claim 2 or 3, **characterized** in that said liquid containers (12, 13) are mounted adjacent to a face of said flow matrix (6), and the separation means comprise a flat liquid-tight element (5) sandwiched between the liquid containers (12, 13) and the flow matrix (6).
5. The test device according to any one of claims 2 to 4, **characterized** in that the liquid-tight element (5) is at least partially removable from the housing (1, 2).
6. The test device according to claim 5, **characterized** in that the liquid-tight element (5) is a pull-out element, e.g. a pull-out sheet or film.

7. The test device according to any one of claims 1 to 6, **characterized** in that the liquid containers (12, 13) are mounted in a movable relationship with the flow matrix (6).

5 8. The test device according to any one of claims 1 to 7, **characterized** in that said at least one liquid container for liquid other than sample liquid comprise at least one container with flow liquid (12), such as a buffer solution.

10 9. The test device according to claim 8, **characterized** in that said liquid container or containers for flow liquid are in the form of an absorbent pad or sponge (12).

15 10. The test device according to any one of claims 1 to 9, **characterized** in that said at least one liquid container for liquid other than sample liquid comprise a container for an analytically detectable reagent.

20 11. The test device according to claim 10, **characterized in that** ^{wherein the} said liquid container for analytically detectable reagent is in the form of an absorbent pad or sponge.

25 12. The test device according to claim 10 or 11, **characterized** in that at least one liquid container for flow liquid is provided upstream and/or downstream of said container with analytically detectable reagent.

30 13. The test device according to any one of claims 1 to 9, **characterized** in that said flow matrix (6) comprises a zone having said analytically detectable reagent pre-deposited in the matrix or in an element (8) placed on the matrix.

35 14. The test device according to claim 13, **characterized in that** ^{wherein} a first container for flow liquid is provided above and along said zone with analytically detectable reagent.

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15. The test device according to claim 14, ~~characterized in that~~ ^{wherein} at least one second container for flow liquid is provided upstream of said first container, and/or at least one third container is provided downstream of said first container.
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16. The test device according to claim 13, ~~characterized in that~~ ^a that a first container (12) for flow liquid extends both upstream of and at least partially above and along said zone with analytically detectable reagent.
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17. The test device according to claim 13, ~~characterized in that~~ ^{wherein} at least one second container for flow liquid is provided downstream of said first container.
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18. The test device according to claim 16 or 17, ~~characterized in that~~ ^a a barrier element (11) extends above said zone (8) with analytically detectable reagent to prevent direct contact between said first container (12) for flow liquid and the zone with analytically detectable reagent, when said separation means (5) is in said second position.
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19. The test device according to any one of claims 1 to 18, ~~characterized in that~~ ^a said capturing agent immobilized in the flow matrix (6) is a member of a specific binding pair and that the other member of the specific binding pair is part of or coupled to a reagent capable of binding the analyte.
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20. The test device according to claim 19, ~~characterized in that~~ ^{wherein the} said specific binding pair is antigen-antibody, hapten-antibody, biotin-avidin, biotin-streptavidin or a nucleic acid duplex.
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21. The test device according to any one of claims 10 to 20, ~~characterized in that~~ ^a said analytically detectable reagent is labelled, such as by a fluorophore or a chromophore.
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22. A method of performing an assay for determining an analyte in a sample, which method comprises flowing sample and assay liquids through a flow matrix to reach a reaction zone in said flow matrix in a predetermined sequence,

characterized in that a device according to any one of claims 1 to 21 is used to carry out the method.

23. Use of the device according to any one of claims 1 to 21 for testing for an analyte indicating a disease selected from allergy, inflammation and autoimmune diseases.

24. The use according to claim 23, wherein the analyte is a specific immunoglobulin.

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25. A kit for conducting an assay method, which kit comprises the device of any one of claims 1 to 21 in combination with other assay component(s).

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